K121171

5. 510(k) Summary

General Company Information

NOV 26 2012

Name: Ivera Medical Corporation
Contact: Don Canal
Vice President of Operations and RAQA

Address: Ivera Medical Corporation
3525 Del Mar Heights Road
Suite #430
San Diego, CA 92130

Telephone: 972-955-7644
Fax: 858-228-1770

Date Prepared: October 23, 2012

General Device Description

The Curos Tips™ are intended for use on IV administration lines Male luer as a disinfecting cleaner, which contains 70% IPA, prior to line connection and to act as a physical barrier to contamination between line accesses. The Curos Tips have a highly visible green color that may allow improved compliance by easy visual verification. The Curos Tips may be used in the home or healthcare facility.

Common Name: **Pad, Alcohol**
Trade Name: **Curos Tips™**
Classification: Unclassified Device, product Code LKB

Predicate Devices

K111992 Curos Port Protector, Ivera Medical Corporation
K093229 Catheter Connections Dual Cap

Intended Use (Indications)

The Curos Tips™ are intended for use as a disinfecting cleaner for male luer connectors. Curos Tips will disinfect the male luer (3) minutes after application and will cover the luer until removed. The effectiveness of the Curos Tips was tested in vitro against Staphylococcus aureus, Staphylococcus epidermidis, Escherichia coli, Pseudomonas aeruginosa, Candida glabrata, and Candida albicans. The Curos Tips may be used in the home or healthcare facility.

Comparison with Predicate Device

Subject Device to Predicate Technological Comparison Table

Characteristic	**Subject Device K121171**	**Curos Port Protector K111992**	**Predicate Device K093229**
Device name	Curos Tips	Curos Port Protector	Dual Cap
Common Name	Alcohol, disinfecting pad	Alcohol, disinfecting pad	Alcohol, disinfecting pad
Manufacturer	Ivera Medical	Ivera Medical	Catheter Connections
510(k) number	Subject Device	K111992	K093992
Regulation number, product code	Unclassified, Preamendment device, product code: LKB	Unclassified, Preamendment device, product code: LKB	Unclassified, Preamendment device, product code: LKB
Indications for use	The Curos Tips™ are intended for use as a disinfecting cleaner for male luer connectors. Curos Tips will disinfect the male luer (3) minutes after application and will cover the luer until removed. The effectiveness of the Curos Tips was tested in vitro against Staphylococcus aureus, Staphylococcus epidermidis, Escherichia coli, Pseudomonas aeruginosa, Candida glabrata, and Candida albicans. The Curos Tips may be used in the home or healthcare facility.	The Curos is intended for use on swab-able luer access valves as a disinfecting cleaner prior to line access and to act as a physical barrier to contamination between line accesses. Curos ™ will disinfect the valve three (3) minutes after application and act as a physical barrier to contamination for up to seven (7) days (168 hours) if not removed. The effectiveness of Curos Protectors were tested in vitro against Staphylococcus aureus, Staphylococcus epidermidis, Escherichia coli and Pseudomonas aeruginosa, Candida glabrata, Candida albicans and was found to have >4 log reduction. The Curos Port Protector may be used in the home or healthcare facility.	DualCap™ is intended for use on Luer access valves and the IV administration line male Luer connections. DualCap™ will disinfect and decontaminate the valve and male Luer and act as a barrier to contamination between IV administration line accesses. DualCap™ will disinfect the connections within five (5) minutes after application and act as a physical barrier to contamination up to ninety-six (96) hours under normal conditions if not removed.
Disinfectant – active ingredient	70% Isopropyl Alcohol	70% Isopropyl Alcohol	70% Isopropyl Alcohol
Male Luer Connection	Yes	No	Yes
Female Luer Connection	No	Yes	Yes
Length	0..76 inches	0.40 inches	1.82 inches
Diameter	0.272 inches	0.54 inches	0.47 inches
User Population	Home and hospital use	Home and hospital use	Home and hospital use

Characteristic	Subject Device K121171	Curos Port Protector K111992	Predicate Device K093229
Colorants Used (type, amount, concentration)	Translucent green, molded plastic, 3% concentration	Translucent green, molded plastic, 3% concentration	Blue, white Plastic, unknown material and pigment(s)
Provided Sterile	Yes	Yes	Yes
Single Use Device	Yes	Yes	Yes
Plastic Housing to remain in place	Yes	Yes	Yes

Substantial Equivalence Performance Testing

Ivera Medical has provided non-clinical performance test data that demonstrates the pre-defined acceptance criteria for a disinfecting device has been met. This acceptance criteria is defined as a bacteria count reduction of ≥ 4 log reduction of 2 selected gram positive bacteria, 2 selected gram negative bacteria, and two selected fungus/yeast micro-organisms for a period of 3 minutes.

The efficacy testing was completed using a total of 6 bacteria. As recommended by the Draft Guidance for Industry and FDA Staff Premarket Notification [510(k)] Submissions for Medical Devices that Include Antimicrobial Agents DRAFT GUIDANCE Ivera completed the 2-gram negative and 2 gram positive bacteria. This guidance document is being distributed for comment purposes only. Document issued on: July 19, 2007. Ivera has also completed testing on 2 fungus/yeast micro-organisms Candida Albicans and Candida Glabrata. The test results are summarized in Table 1.

Table 1 - Efficacy Test Results

Organism	Acceptance Criteria (bacterial count reduction (ΔLog))	3 minute exposure (bacterial count reduction (ΔLog))
Staphylococcus aureus	**≥4 Log**	**6.61**
Staphylococcus epidermis	**≥4 Log**	**6.48**
Escherichia coli	**≥4 Log**	**6.53**
Pseudomonas aeruginosa	**≥4 Log**	**6.49**
Candida Albicans	**≥4 Log**	**6.60**
Candida Glabrata	**≥4 Log**	**6.64**

The Ivera Curos Tips are sterilized using a validated Gamma sterilization process which complies with ISO11137-1:2006/(R) Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose. Recognition number 14-225.

ISO11137-2:2006 Sterilization of health care products – Radiation – Part 1: requirements for development of validation and routine control of sterilization process for medical devices. Recognition number 14-297.

11137-3:2006/(R) 2010 10/04/2010 AAMI ANSI ISO 14-298 - Radiation - Part 3: Guidance on Dosimetric Aspects. Recognition number 14-298.FDA recognized standard ISO11137 Sterilization Standard.

Ivera Medical has completed testing to demonstrate the materials of construction for the Subject Device meet FDA recognized standard ISO10993 for biocompatibility.

Conclusion

The analysis arguments and test results demonstrate the Curos Tips™ device is safe for its intended use and is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

NOV 26 2012

Mr. Don Canal
Vice President of Operations and Regulatory Affairs and Quality Assurance
Ivera Medical, Incorporated
3525 Del Mar Heights Suite #430
San Diego, California 92010

Re: K121171
Trade/Device Name: Curos Tips™
Regulation Number: Unclassified
Regulation Name: Pad, Alcohol
Regulatory Class: Unclassified
Product Code: LKB
Dated: October 23, 2012
Received: October 25, 2012

Dear Mr. Canal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

The Curos Tips™ are intended for use as a disinfecting cleaner for male luer connectors. Curos Tips will disinfect the male luer (3) minutes after application and will cover the luer until removed. The effectiveness of the Curos Tips was tested in vitro against Staphylococcus aureus, Staphylococcus epidermidis, Escherichia coli, Pseudomonas aeruginosa, Candida glabrata, and Candida albicans. The Curos Tips may be used in the home or healthcare facility.

Prescription Use ☑ **AND/OR Over-The-Counter Use** ☐

(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by Richard C. Chapman
Date: 2012.11.21 11:26:03 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K121171